

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE **10/573821**

In re Application of: Kazuaki OKUNO et al. )

Application No.: NEW )  
(National Stage of PCT/JP2004/014704 )  
Filed September 29, 2004) )

Confirmation No.: Unassigned

Group Art Unit: Unassigned

Examiner: Unassigned

Filed: March 28, 2006 )

For: POLYPEPTIDE CLEAVAGE METHOD USING OmpT PROTEASE VARIANT

Commissioner for Patents

U.S. Patent and Trademark Office

Customer Window Mail Stop: ☒ New Application ☐ Amendment ☐ AF ☐ Issue Fee  
Alexandria, VA 22314

Sir:

**INFORMATION DISCLOSURE STATEMENT (IDS)**

☒ **Under 37 C.F.R. § 1.97(b):** Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicant brings to the attention of the Examiner the documents listed on the attached PTO Form 1449. To the undersigned's knowledge, this IDS is being filed before the mailing date of a first Office Action on the merits, before the mailing date of a first Office Action on the merits after filing an RCE under § 1.114, or within three months of the application filing date.

☐ **Under 37 C.F.R. § 1.97(c):** Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents listed on the attached PTO Form 1449. This IDS is being filed after the events recited in § 1.97(b) but, to the undersigned's knowledge, before the mailing date of a Final Office Action, a Notice of Allowance, or another action that closes prosecution in the application.

☐ The fee of \$180.00 set forth in § 1.17(p) is included herein; or

☐ Applicant submits that each item of information contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.

☐ **Under 37 C.F.R. § 1.97(d):** Pursuant to 37 C.F.R. §§ 1.56 and 1.97(d), Applicant brings to the attention of the Examiner the documents listed on the attached PTO Form 1449. This IDS is being filed after the events recited in § 1.97(c) but before payment of the issue fee.

☐ The fee of \$180.00 set forth in § 1.17(p) is included herein; and

☐ Applicant submits that each item of information contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.

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☐ **Under 37 C.F.R. § 1.97(i):** Pursuant to 37 C.F.R. §§ 1.56 and 1.97(i), Applicant brings to the attention of the Examiner the documents listed on the attached PTO Form 1449. This IDS is being filed after the events recited in § 1.97(d). Applicant requests that the IDS be placed in the file.

☒ A search report or other listing of documents from a counterpart, related, or other application dated December 28, 2004 and having documents cited thereon is attached for the Examiner's consideration. Any of these documents not previously cited, and any additional documents are listed on the PTO Form 1449.

☒ Applicant respectfully requests that the Examiner consider the listed documents and evidence that consideration by making appropriate notations on the attached form. As for any document listed on the accompanying PTO-1449 that is in a language other than English, relevance can be understood from an enclosed English abstract or at least partial translation or from mention in the specification or in a search report for a corresponding application.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that any of the listed documents are material or constitute "prior art." If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

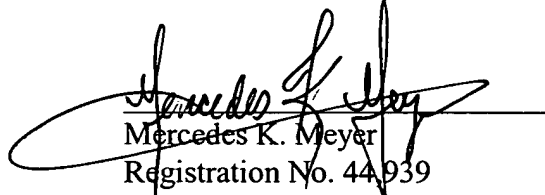
Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should any of the documents be applied against the claims of the present application.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this Application, including fees due under 37 C.F.R. § 1.16 and 1.17 which may be required and including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0573. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

**DRINKER, BIDDLE & REATH LLP**

Dated: March 28, 2006

  
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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)			Attorney Docket No.: 47259-5001-00 US			Serial No.: <b>NEW</b>		
PTO Form 1449			Applicants Kazuaki OKUNO et al.			Page 1 of 1 <b>10/ 573821</b>		
			Filing Date: March 28, 2006			Group Art Unit: Unassigned		
U.S. PATENT DOCUMENTS								
*Examiner Initial		Document Number	Date	Name	Class	Sub Class	Filing Date	
FOREIGN PATENT DOCUMENTS								
		Document Number	Date	Country	Class	Sub Class	<u>Translation</u> YES NO	
OTHER DOCUMENTS								
(Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)								
	R.A. KRAMER et al., "Identification of Essential Acidic Residues of Outer Membrane Protease OmpT Supports a Novel Active Site", FEBS Letters, 2001, pp. 426-430, Vol. 505, Published by Elsevier Science B.V.							
	Kazuaki OKUNO et al., "Substrate Specificity at the P1' Site of <i>Escherichia coli</i> OmpT Under Denaturing Conditions", Biosci. Biotechnol. Biochem., 2002, pp. 127-134, Vol. 66, No. 1.							
	Niek DEKKER et al., "Substrate Specificity of the Integral Membrane Protease OmpT Determined by Spatially Addressed Peptide Libraries", Biochemistry, 2001, pp. 1694-1701, Vol. 40, No. 6., Published by American Chemistry Society.							
	Kazuaki OKUNO et al., "An Analysis of Target Preferences of <i>Escherichia coli</i> Outer-Membrane Endoprotease OmpT for Use in Therapeutic Peptide Production: Efficient Cleavage of Substrates With Basic Amino Acids at the P4 and P6 Positions", Biotechnol. Appl. Biochem., 2002, pp. 77-84, Vol. 36 (Pt. 2), Published by Portland Press Ltd., Printed in Great Britain.							
	Kazuaki OKUNO et al., "Utilization of <i>Escherichia coli</i> Outer-Membrane Endoprotease OmpT Variants as Processing Enzymes for Production of Peptides From Designer Fusion Proteins", Applied and Environmental Microbiology, Jan. 2004, pp. 76-86, Vol. 70, No. 1, Published by American Society for Microbiology.							
Examiner					Date Considered			
Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								